Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

2289 5 JUL -7 A9:34

June 28, 2005

Subject: Supplement to Docket No. 2004P-0013

Dear Sir or Madam,

My Citizen Petition requested that the Commissioner (1) review the safety of Nutropin Depot. Genentech Inc. Application manufactured it no: 21-075 and approved on 12/22/00.

The following circumstances have changed:

On June 1, 2004 Genentech and Alkermes announced their decision to discontinue commercialization of Nutropin Deport. They stated their decision was based on the significant resources required to produced and commercialize the product.

On May 21, 2005 Genentech and Ipsen agree to develop sustained-release formulations of recombinant human growth hormone.

My present concern is that, on February 14, 2001 I e-mailed Genentech's Medical Information Department, (see attachment #1) which included questions I had concerning the safety of Nutropin Depot. One of these questions NO. 5 - What effect would this increase in dosage have upon the body, if the time release agent was inert or non-effective. This question was never addressed or answered by Genentech. It is my contention that, the possibility of Aldermes sustained-release component to the Nutropin Depot being inept or non-effective is plausible. If inept or none-effective, the result would be, an injection of a 14-day supply of growth hormone in a single injection. That's 14 times what a single injection found to be safe in clinical trials.

I am aware that, the FDA has the authority to request data from private drug manufactures databases, if cause is apparent. Genentech's agreement with Ipsen to produce a sustained-release formulation as they had with Alkermes, leads me to believe they had sufficient reports of serious adverse reactions to the Nutropin Depot preparation, to suspend it production, and seek another manufacturer of a sustained-release formulation. The only way to ascertain the truth with any certainty is to request from Genentech's database, all reports of serious adverse reactions to their growth hormone products.

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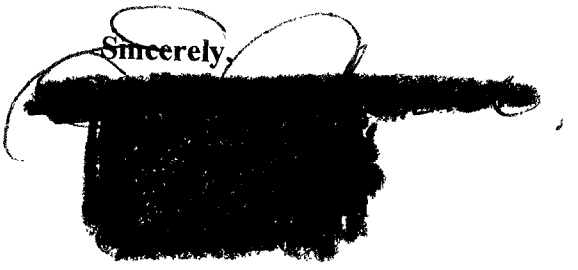
Thank you for your time and consideration.

Sincerely,



Attachment #1

Subj: Questions Regarding [redacted] Onset of Type 1 Diabetes - Nutropin Depot
Date: 2/14/2001 2:47:03 PM Eastern Standard Time
From: [redacted]
To: [redacted]

From: [redacted]

To: Medical Information Department, Genentech, Inc.

Dear Sir.

I was directed to contact your department by your Drug Safety Division. My daughter [redacted] DOB [redacted] She Turner Syndrome (TS). She was on Nutropin AQ for almost 3 years with excellent growth results and no adverse reactions. She was prescribed Nutropin Depot and received her 1st set infections on 10/12/2000. That evening she had a blood discharge which we assumed to be her period. Subsequently we found out that girls with TS don't normally get their period until they start on estrogen. Her 2nd set of injections were given 14 days later. Emuli was used at the injection sites (legs). The areas became black and blue, very hot and painful to the touch. Her endocrinologist told use to take her to see a doctor to insure there were no infections. There weren't any These areas still show distinctive outlines of where the injections were given. At this time she began to show signs of unusual hunger and thirst. We thought this was a normal reaction to the increase in the GH. After her 3rd set of injections, the next day she was feeling sick all day at school, and that night she became very ill. Early the next morning were took her to the emergency room, where urine tests indicated she had high sugar levels.

Questions.

1. How many TS girls were in your clinical studies of Nutropin Depot?
2. Are any TS girls presently taking Nutropin Depot?
3. Have any of these TS girls reported adverse effects?
4. What percentage increase in the dosage of somatropin were we injecting into Lauren with the Nutropin Depot Vs Nutropin AQ?
5. What effect would this increase in dosage have upon the body, if the time release agent was inert or non-effective?
6. Lauren was given a Hemoglobin A1C (HbA1C) test at time of admittance to the hospital. Her Endocrinologist nurse stated that the time of the onset of the high sugar levels was about the time of the administering of the Nutropin Depot. What does this result imply to you?
7. Was Emuli used on any of the subjects of the clinical studies? Were the any allergic or adverse reports to its use?
8. In the section on Overdose (Genentech Products), what testing results prompted the inclusion of hyperglycemia as an outcome?

If you need any further information from me or releases of my daughters medical records to assist you in your investigation, please contact me. Please further, keep me informed as to the progress at the different stages Thank you for your time and consideration,

Sincerely,

[redacted]